

# **EXHIBIT B-1**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	C.A. No. 21-1286 (MSG)
	)	C.A. No. 21-1455 (MSG)
v.	)	
	)	
BIONPHARMA INC.,	)	
	)	
Defendant.	)	

**PLAINTIFF AZURITY PHARMACEUTICALS, INC.’S INITIAL INFRINGEMENT  
CLAIM CHARTS**

Pursuant to Paragraph 7(c)(iv) of the Court’s Scheduling Order, (21-1286, D.I. 126) and Paragraph 4(c) of the District of Delaware’s Default Standard for Discovery (“Default Standard”), Plaintiff Azurity Pharmaceuticals, Inc. (“Azurity”) herein provides its initial infringement contentions with corresponding initial infringement claim charts to Defendant Bionpharma Inc. (“Bionpharma”). Azurity is asserting infringement of the following patents in the above-captioned matters:

- U.S. Patent No. 11,040,023 (the ““023 patent””)
- U.S. Patent No. 11,141,405 (the ““405 patent””)

Azurity’s disclosures are based on the information reasonably available to Azurity at present. Azurity reserves the right to supplement or modify these disclosures as additional information is obtained. Azurity reserves all rights to amend and supplement these initial infringement contentions and corresponding claim charts in according with the Court’s orders, Local Rules, and the Federal Rules of Civil Procedure as appropriate.

Discovery is currently ongoing, and additional facts, documents, things, and testimony—whether presently known or unknown to Azurity—may become relevant. Azurity further reserves

the right to amend, alter, or supplement these initial infringement contentions and corresponding claim charts based on any further investigation, fact, or expert discovery, and any contentions or positions taken by Bionpharma and/or its designated experts. By providing these initial infringement contentions and corresponding claim charts, Azurity does not waive any right to introduce at trial any subsequently discovered or developed evidence or expert opinions. Azurity reserves the right to refer to, conduct discovery with reference to, or offer into evidence at the time of trial, any and all facts, expert opinions, documents, and things notwithstanding the statements in these initial infringement contentions and corresponding claim charts. Azurity also reserves its right to refer to, conduct discovery with reference to, or offer into evidence at the time of trial, any and all facts, documents, and things that are not currently recalled or might be recalled at some time in the future. Azurity may rely on documents, testimony, and things produced in the course of fact and expert discovery, including those which have not yet been produced by Bionpharma or which Azurity has not yet identified or appreciated the significance of in the context of this litigation. Moreover, Azurity reserves the right to adduce additional evidence in support of its current or future positions.

Initial infringement claim charts with respect to each of the '023 and '405 patents are attached as—respectively—Exhibits A and B. Azurity includes in these exhibits exemplary references to Bionpharma's ANDA No. 212408 and other evidence available at this time. Azurity reserves the right to add or modify the claims asserted for each of the '023 and '405 patents and/or the contentions relating to infringement, including based on additional review, analysis, and information identified in fact and expert discovery, and/or any further information submitted to the FDA regarding Bionpharma's ANDA No. 212408.

## **BIONPHARMA'S INFRINGEMENT**

Azurity contends that Bionpharma's submission of ANDA No. 212408 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act seeking permission to manufacture, market, use, and sell a generic version of Azurity's enalapril maleate oral solution that is the subject of New Drug Application No. 208686 and actually producing and selling such a generic product before the expiration of the '023 and '405 patents constitutes infringement—either directly or indirectly; literally or under the doctrine of equivalents—of at least the following claims under 35 U.S.C. § 271(a)-(c) and 35 U.S.C. § 271(e)(2)(A).

<b>Patent</b>	<b>Asserted Claims</b>
'023 patent	1-6, 10-16, 19
'405 patent	1, 2, 6, 7, 10, 12, 13, 14, 17, 19, 20, 22

[REDACTED]

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*/s/ Megan E. Dellinger*

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April 18, 2022

**CERTIFICATE OF SERVICE**

I hereby certify that on April 18, 2022, copies of the foregoing were caused to be served upon the following in the manner indicated:

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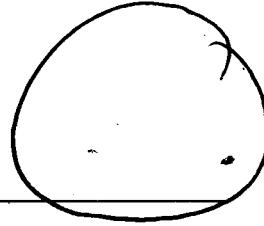
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Megan E. Dellinger (#5739)

# **EXHIBIT B-2**

MSG

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA



KING DRUG COMPANY OF FLORENCE, INC., <u>et al.</u> , Plaintiffs, v. CEPHALON, INC., <u>et al.</u> , Defendants.	CIVIL ACTION No. 2:06-cv-1797 ✓
VISTA HEALTHPLAN, INC., <u>et al.</u> , Plaintiffs, v. CEPHALON, INC., <u>et al.</u> , Defendants.	CIVIL ACTION No. 2:06-cv-1833 ✓
APOTEX, INC., Plaintiff, v. CEPHALON, INC., <u>et al.</u> , Defendants.	CIVIL ACTION No. 2:06-cv-2768 ✓
FEDERAL TRADE COMMISSION, Plaintiff, v. CEPHALON, INC., Defendant.	CIVIL ACTION No. 2:08-cv-2141 ✓

**SCHEDULING ORDER**

**AND NOW**, this 26th day of April, 2010, following a preliminary pretrial conference, it is

**ORDERED** that:

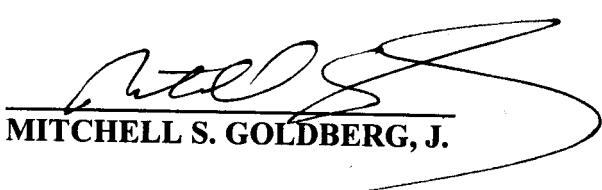
1. The parties shall make their initial disclosures pursuant to FED. R. CIV. P. 26(a) by May 5, 2010, if they have not already done so.
2. All fact discovery, including class discovery, shall begin immediately and must be completed by February 11, 2011.
3. Each party may propound up to thirty-five (35) interrogatories, without subparts, without seeking leave of Court.
4. Each party may conduct up to fifteen (15) depositions without seeking leave of Court.
5. Only two (2) attorneys per party may attend depositions. For the duration of the deposition, only one (1) of those two (2) attorneys may ask questions and/or if defending the deposition, raise objections.
6. Pursuant to FED. R. CIV. P. 30(c)(2), witnesses may only be instructed not to answer questions based on a recognized privilege.
7. Paragraph 22 of the Court's February 19, 2010, Scheduling Order in the Apotex v. Cephalon, 2:06-cv-2768, patent case is modified to reflect that one (1) counsel per party in the consolidated antitrust cases may attend depositions in the Apotex v. Cephalon patent case. Antitrust counsel may not ask questions or raise objections during the depositions. All scheduling shall be strictly between patent counsel; depositions will not be rescheduled due to a scheduling conflict with antitrust counsel.
8. Counsel must meet and confer regarding any and all discovery disputes before

submitting them to the Court for review. The certification required under LOCAL R. CIV. P. 26.1(f) must state what efforts were made to resolve the dispute. If the Court's intervention is required, the Court may impose sanctions in favor of the prevailing party, if warranted.

9. The Court encourages the submission of routine discovery disputes through the submission of correspondence outlining the issues in dispute. Correspondence shall not exceed three (3) pages and shall not include exhibits. Responsive correspondence is expected to be submitted within three (3) business days. Upon review of the discovery dispute correspondence, the Court may schedule a telephone conference. If a motion to compel is filed under LOCAL R. CIV. P. 26.1(g), the motion shall not exceed five (5) pages, shall not contain exhibits, and shall not include a brief or memorandum of law, unless the motion involves the invocation of a privilege.
10. Plaintiffs shall produce their expert report(s) by March 11, 2011. Defendants shall produce their expert report(s) by April 15, 2011. Plaintiffs' expert witness rebuttal reports (if necessary) shall be produced by April 29, 2011. All expert discovery, including all depositions of expert witnesses, shall be completed by May 27, 2011.
11. Any party expecting to offer opinion testimony from lay witnesses pursuant to Federal Rule of Evidence 701 with respect to the issues of liability and/or damages shall, within the time required for the submission of expert discovery set forth above, serve opposing parties with concise details and/or documents covering the lay opinions of the Rule 701 witnesses, including the identity of each witness offering the expert opinion, the substance and the basis for each opinion.

12. After reviewing the claim construction briefs and dispositive motions submitted in the Apotex v. Cephalon patent case, if necessary, antitrust counsel may seek leave of Court to submit supplemental briefs. Such motions shall be filed no later than seven (7) days after the filing of the brief which counsel seeks to supplement. The motion must specifically identify the issues not addressed in the original brief and specify the supplemental issues that counsel intends to address.
13. All motions for summary judgment and *Daubert* motions shall be filed no later than June 17, 2011.
14. Responses to motions for summary judgment and *Daubert* motions, if any, shall be filed no later than July 8, 2011.
15. All motions for summary judgment and responses thereto are limited to fifty (50) pages. All *Daubert* motions and responses thereto are limited to twenty-five (25) pages.
16. If necessary, the Court will issue a briefing schedule for the motions for class certification after ruling on the dispositive motions.
17. Counsel are referred to Judge Restrepo for settlement and should consult his Chambers for the scheduling and handling of all matters related thereto.
18. Absent compelling circumstances, no extensions of this Scheduling Order will be granted.

**BY THE COURT:**

  
MITCHELL S. GOLDBERG, J.

# **EXHIBIT B-3**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES, an Illinois corporation, FOURNIER INDUSTRIE ET SANTÉ, a French corporation, and LABORATOIRES FOURNIER S.A., a French corporation,	)	
Plaintiffs,	)	
v.	)	C.A. No. 02-1512 (KAJ)
TEVA PHARMACEUTICALS USA, Inc., a Delaware corporation,	)	(consolidated)
Defendant,	)	
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TEVA PHARMACEUTICALS USA, Inc., a Delaware corporation, and TEVA PHARMACEUTICAL INDUSTRIES LTD., an Israeli corporation,	)	
Counterclaim Plaintiffs,	)	
v.	)	
ABBOTT LABORATORIES, an Illinois corporation, FOURNIER INDUSTRIE ET SANTÉ, a French corporation, and LABORATOIRES FOURNIER S.A., a French corporation,	)	
Counterclaim Defendants,	)	
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ABBOTT LABORATORIES, an Illinois corporation, FOURNIER INDUSTRIE ET SANTÉ, a French corporation, and LABORATOIRES FOURNIER S.A., a French corporation,	)	
Plaintiffs,	)	C.A. No. 03-120 (KAJ)
v.	)	(Consolidated)
IMPAX LABORATORIES, INC., a Delaware corporation	)	
Defendant.	)	
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**SCHEDULING ORDER**

This 27<sup>th</sup> day of October, 2005, the Court having conducted an initial Rule 16 scheduling and planning conference pursuant to Local Rule 16.2(a) on July 27, 2005, and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration;

IT IS ORDERED that:

1. Rule 26(a)(1) Initial Disclosures. Unless otherwise agreed to by the parties, the parties shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) by September 15, 2005.

2. Production of Patent Litigation Materials. By August 31, 2005, Teva and Impax will allow access to all prior discovery in this case to the parties in the litigation referred to as In re TriCor Direct Purchaser Antitrust Litigation and In re TriCor Indirect Purchaser Antitrust Litigation (hereinafter the “Purchaser Actions”). Those materials shall be treated in the Purchaser Actions in accordance with Local Rule 26.2 until an appropriate protective order is entered in those actions.

3. Amendment of Pleadings and Rule 12 Briefing Schedule. All parties shall file first amended counterclaims, if they intend to do so, by no later than September 23, 2005. Thereafter, the following briefing schedule applies to any motions to dismiss to be filed against those pleadings under Rule 12:

a.	Opening briefs filed:	October 19, 2005
b.	Responding briefs filed:	December 2, 2005
c.	Reply briefs filed	December 22, 2005

Discovery is not stayed, and the pendency of any potentially dispositive motions, under Rule 12 or otherwise, shall not relieve any party of its obligations to respond to discovery requests and produce responsive discovery in a timely manner.

4. Joinder of Other Parties and Amendment of Pleadings. All subsequent motions to join other parties, and to amend or supplement the pleadings further shall be filed on or before April 1, 2006.

5. Discovery

a. Document Production. Any party may serve document requests on or after September 1, 2005. As to any document requests served on or before October 1, 2005, production of responsive documents shall be completed by February 15, 2006. The existence of the February 15, 2006 deadline is not a ground for undue delay in producing documents prior to February 15. Nothing in this paragraph shall preclude a party from serving document requests at any time, so long as the timing of those requests is consistent with the discovery deadlines set forth in Paragraphs 5f and 5g below. The deadlines in the Paragraph 5a do not apply to the production contemplated in Paragraph 5b below.

b. Production of Documents Submitted to the FTC. Any party that has submitted documents to the United States Federal Trade Commission (“FTC”), whether voluntarily or pursuant to compulsory process, in connection with the FTC investigation identified as Abbott Laboratories, File 005-0124, shall produce those documents to all other parties, including the parties to the Purchaser Actions. Production of such documents shall begin immediately upon entry of this order. All documents submitted to the FTC as of August 1, 2005, shall be produced in this litigation by no later

than September 15, 2005, and any additional documents shall be produced within twenty-one days after they are submitted to the FTC, but no earlier than September 15, 2005. Documents to be produced shall include all correspondence to or from the FTC concerning the document submissions and all logs concerning the documents. The FTC documents shall be treated in the Purchaser Actions in accordance with Local Rule 26.2 until an appropriate protective order is entered in those actions.

c. Location of Depositions. Any party or representative (officer, director, or managing agent) of a party filing a civil action in this district court must ordinarily be required, upon request, to submit to a deposition at a place designated within this district. Exceptions to this general rule may be made by order of the Court. A defendant who becomes a counterclaimant, cross-claimant, or third-party plaintiff shall be considered as having filed an action in this Court for the purpose of this provision. Notwithstanding the general rule, and without waiving any party's right to require that depositions be held in this district and be taken in accordance with the procedures set forth in the Federal Rules, the parties will cooperate to schedule depositions in locales that are practical given the locations (which include foreign countries) and schedules of the witnesses.

d. Timing of Depositions. No depositions in this matter shall be noticed to occur prior to January 16, 2006.

e. Other Fact Discovery. Any party may serve interrogatories, requests to admit, or any other request for written discovery on or after September 1, 2005.

f. Fact Discovery Cut Off. All fact discovery in this case shall be initiated so that it will be completed on or before October 31, 2006. Unless otherwise ordered by the Court, the limitations on discovery set forth in Local Rule 26.1 shall be strictly observed.

g. Expert Testimony. Any party bearing the burden of proof on any issue shall file its initial Federal Rule of Civil Procedure 26(a)(2) disclosures of expert testimony concerning that issue on or before December 15, 2006. Any party may file an opposing expert report to contradict or rebut evidence on the same subject matter identified by another party on or before January 30, 2007. Any party filing an initial expert report shall be entitled to file a reply report on or before February 28, 2007. Expert depositions shall be completed by March 30, 2007. To the extent any objection to expert testimony is made pursuant to the principles announced in Daubert v. Merrell Dow Pharm., Inc. 509 U.S. 579 (1993), it shall be made by motion no later than the deadline for dispositive motions set forth herein, unless otherwise ordered by the Court.

h. Discovery Disputes. Should counsel find they are unable to resolve a discovery dispute, the party seeking the relief shall contact chambers at (302) 573-6001 to schedule a telephone conference, and shall notify all other parties on the same day that it has done so. Not less than forty-eight hours prior to the conference, the party seeking relief shall file with the Court a letter, not to exceed three pages, outlining the issues in dispute and its position on those issues. (The Court does not seek extensive argument or authorities at this point; it seeks simply a statement of the issue to be addressed and or summary of the basis for the party's position on the issue.) Not less than twenty-four hours prior to the conference, any party opposing the application for

relief may file a letter, not to exceed three pages, outlining that party's reasons for its opposition. Should the Court find further briefing necessary upon conclusion of the telephone conference, the Court will order it. Disputes over protective orders are to be addressed in the first instance in accordance with this paragraph.

6. Protective Order. The Protective Order entered during the patent phase of this litigation shall continue in effect in these actions. The parties may propose changes to the Protective Order as may be appropriate for the antitrust phase of the case.

7. Papers Filed Under Seal. When filing papers under seal, counsel should deliver to the Clerk an original and one copy of the papers.

8. Quarterly Status Reports. Pursuant to Local Rule 16.1(b)(1), the parties will file a joint quarterly status report on November 15, 2005, and every three months thereafter, unless a different schedule is ordered by the Court. The reports will cover the status of discovery and any motions or other procedural matters that are pending or anticipated.

9. Status Conference. On May 22, 2006, the Court will hold a Rule 16(a), (b) and (c) conference by telephone with counsel beginning at 4:30 p.m. Plaintiff's counsel shall initiate the telephone call. If all parties agree that there is nothing to report, nor anything to add to the interim status report or to this order, they may so notify the Court in writing before the conference is scheduled to occur, and the conference will be taken off of the Court's calendar.

10. Case Dispositive Motions. All case dispositive motions, an opening brief, and affidavits, if any, in support of the motion shall be served and filed on or before May

2, 2007. Responding briefs shall be filed on or before June 1, 2007 and reply briefs shall be filed on or before June 22, 2007.

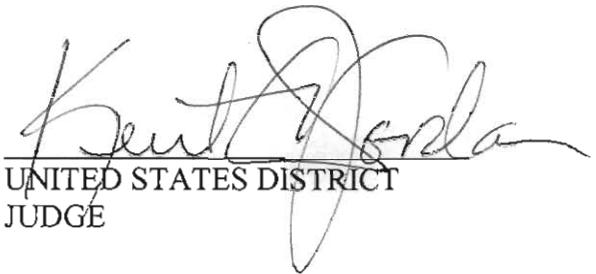
11. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion filed with the Clerk. Unless otherwise requested by the Court, counsel shall not deliver copies of papers or correspondence to Chambers. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

12. Pretrial Conference. On October 22, 2007, the Court will hold a Final Pretrial Conference in Chambers with counsel beginning at 4:30 p.m. Unless otherwise ordered by the Court, the parties should assume that filing the pretrial order satisfies the pretrial disclosure requirement of Federal Rule of Civil Procedure 26(a)(3). The parties shall file with the Court the joint proposed final pretrial order with the information required by the form of Final Pretrial Order which accompanies this Scheduling Order on or before September 24, 2007.

13. Motions in Limine. Motions *in limine* shall not be separately filed. All *in limine* requests and responses thereto shall be set forth in the proposed pretrial order. The *in limine* request and any response shall contain the authorities relied upon; each *in limine* request may be supported by a maximum of five pages of argument and may be opposed by a maximum of five pages of argument. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single five (5) page submission, unless otherwise ordered by the Court. No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

14. Jury Instructions, Voir Dire, and Special Verdict Forms. Where a case is to be tried to a jury, pursuant to Local Rules 47 and 51 the parties should file proposed voir dire, instructions to the jury, and special verdict forms and jury interrogatories three full business days before the final pretrial conference. That submission shall be accompanied by a computer diskette (in WordPerfect format) which contains the instructions, proposed voir dire, special verdict forms, and jury interrogatories.

15. Trial. This matter is scheduled for a three week jury trial beginning at 9:30 a.m. on November 26, 2007. Each side shall have 36 hours to present its case.

  
\_\_\_\_\_  
UNITED STATES DISTRICT  
JUDGE

# **EXHIBIT B-4**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY  
LIMITED, TAKEDA PHARMACEUTICALS  
U.S.A., INC., and TAKEDA  
PHARMACEUTICALS AMERICA, INC.,

Plaintiffs,

v.

ZYDUS PHARMACEUTICALS (USA) INC.  
and CADILA HEALTHCARE LIMITED,

Defendants.

Civil Action No. 3:18-cv-01994-FLW-TJB

**[PROPOSED]  
SCHEDULING ORDER**

The Court having received the parties proposed schedule for the above-captioned action; and for good cause shown,

IT IS on this 7<sup>th</sup> day of January, 2019,

**ORDERED** that the following schedule is hereby entered for the above-captioned action:

Event	Joint Proposed Dates
Takeda to provide documents identified in Section B(4) of Plaintiffs' Rule 26(a) Initial Disclosures	February 15, 2019
Zydus to provide documents identified in Section B of Defendants' Rule 26(a) Initial Disclosures	
Takeda to provide documents identified in Section B(5) of Plaintiffs' Rule 26(a) Initial Disclosures	February 28, 2019
Substantial Completion of Document Production	June 10, 2019
Deadline to amend the pleadings or add parties	July 8, 2019
Close of Fact Discovery	October 23, 2019
Opening Expert Reports	December 7, 2019
Rebuttal Expert Reports	February 5, 2020
Deadline for Expert Discovery	March 13, 2020
Deadline to File Dispositive Motions	April 23, 2020
Opposition Briefs to Dispositive Motions	30 days after filing of opening brief
Reply Briefs in Support of Dispositive Motions	23 days after filing of opposition brief

Pretrial Submissions	TBD
Pretrial Conference	TBD
Trial	TBD



**HON. TONIANNE J. BONGIOVANNI**  
United States Magistrate Judge

A telephone conference shall be held on March 7, 2019  
at 10:30 a.m. Plaintiffs shall initiate the conference.